## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Food and Drug Administration** 

[Docket No. 2004F-0455]

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Sterigenics International, Inc.; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Sterigenics International, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ionizing radiation in the production of shelf stable foods, including multiple ingredient shelf stable foods.

FOR FURTHER INFORMATION CONTACT: Lane A. Highbarger, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1204.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 3M4744) has been filed by Sterigenics International, Inc., P.O. Box 17349, Memphis, TN 31817–0349. The petition proposes that the food additive regulations in part 179 Irradiation in the Production, Processing and Handling of Food (21 CFR 179) be amended to provide for the safe use of ionizing radiation in the production of fully cooked shelf stable foods, including fully cooked multiple ingredient shelf stable foods, where the absorbed dose required to cause a 12-log reduction in Clostridium botulinum has been established.

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The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: Och 28, 2004

October 28, 2004.

Laura M. Tarantino,

Deputy Director,

Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

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